



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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4/16/98

CERTIFIED - RETURN RECEIPT REQUESTED

19900 MacArthur Blvd., Ste 300
Irvine, California 92715-2445
Telephone (714) 798-7600

April 1, 1998

WARNING LETTER

Don Van
General Manager
EQyss International, Inc.
2755 Dos Aarons Way
Vista, CA 92083

WL-25-8

Dear Mr. Van:

As a result of an inspection conducted at your facility, samples of your products were collected, which included container labels and promotional material. Our review of this labeling finds that a number of your products are new animal drugs which are not the subject of approved New Animal Drug Applications. The products are, therefore, being marketed in violation of the Federal Food, Drug, and Cosmetic Act (the Act).

Under the Act, any article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease to man or other animals, or intended to affect the structure or function of man or other animals, is regarded as a "drug". Unless a drug is generally recognized by qualified scientific experts as safe and effective for its labeled uses, it is a new animal drug under the law. A new animal drug may not be legally marketed unless it is the subject of an approved New Animal Drug Application (NADA). Therefore, the following products are unapproved new animal drugs, since they are not generally recognized as safe and effective for the indications for use in their labeling. These products are, therefore, adulterated within the meaning of Section 501(a)(5) of the Act:

Micro Tek Equine Spray: Eliminates fungal, viral, and bacterial skin problems on contact; adds protein to strengthen damaged areas; and is effective on rain rot, scratches, and ringworm.

Micro Tek Equine Shampoo: Controls fungal, viral, and bacterial skin problems upon contact and is effective on rain rot, scratches, and ringworm.

Mega Tek Cell Rebuilder: COAT-Accelerates growth, HOOF-Accelerates regrowth, Strengthens wall, Accelerates regrowth on bare spots caused by skin conditions or injuries. Makes hoofs grow from 10% to 50% faster and makes them 30% stronger. Quarter cracks heal faster

and shoes hold better, especially good for shelly footed horses.

Micro Tek Pet Spray and Shampoo: Eliminates fungal, viral, and bacterial skin conditions such as: flea bite dermatitis, seborrhea, hot spots, dry itchy skin, mange and ear mites, and controls ringworm.

This letter does not represent a comprehensive review of all the products your firm distributes. It is your responsibility to assure that your products are in compliance with the Act.

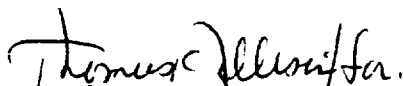
You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

Within fifteen (15) working days of receipt of this letter, notify this office in writing of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your reply should be addressed to:

Mary M. LoVetere, Compliance Officer
Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612-2445

Sincerely,


Elaine E. Messa
District Director

cc: State Department of Public Health
Environmental Health Services
Attn: Stuart P. Richardson, Jr.
Chief Food and Drug Branch
714 "P" Street, Room 400
Sacramento, CA 95814